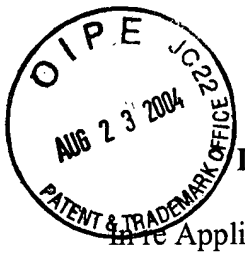
AF/3739



Docket No. 2024729-7019673001
(268/214)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Joseph V. Koblish, et al

Serial No.: 09/975,393

Filed: October 10, 2001

For: DEVICES AND METHODS FOR CREATING LESIONS IN ENDOCARDIAL AND SURROUNDING TISSUE TO ISOLATE FOCAL ARRHYTHMIA SUSTRATES

Group Art Unit: 3739

Confirmation No.: 2510

Examiner: Rollins, Rosiland Stacie

APPEAL BRIEF TRANSMITTAL

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir,

Transmitted herewith is Appeal Brief (15 pages) in triplicate, for the above-identified application.

The items checked below are appropriate.

☒ Appeal Brief Fee:

- ☒ Large Entity Fee of $330.00; or
- ☐ Small Entity Fee of $165.00.
- ☐ Applicant(s) claim Small Entity Status under 37 CFR § 1.27.

☒ Return Receipt Postcard

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, Mail Stop Appeal Brief - Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

8/18/04
Date

Jocelyn L. Lee

OC/206979.1

☒ Please charge Bingham McCutchen's Deposit Account No. **50-2518** in the amount of $330.00.

☒ The Commissioner is authorized to charge Bingham McCutchen's Deposit Account No. **50-2518** for any fees required that are not covered, in whole or in part, and to credit any overpayments to said Deposit Account No. **50-2518**

Respectfully submitted,

BINGHAM McCUTHEN LLP

Dated: 8/10/04 By: _____
Michael J. Bolan
Reg. No. 42,339

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AF/3739
IFW

PATENT
24729-7019673001
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APPEAL BRIEF-CFR 1.192

ATTN: Board of Patent Appeals and Interferences
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Brief is in furtherance of the Notice of Appeal filed herewith, and contains the following items in the order indicated below as required by C.F.R. §1.192:

I. Real Party in Interest
II. Related Appeals and Interferences
III. Status of Claims
IV. Status of Amendments
V. Summary of Invention
VI. Issues
VII. Grouping of Claims
VIII. Arguments
IX. Appendix of Claims Involved in the Appeal

I. Real Party in Interest

The real party in interest in this appeal is Scimed Life Systems, Inc., a corporation organized under the laws of Minnesota.

II. Related Appeals and Interferences

There are no appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. Status of Claims

This application includes claims 1-61. Of these claims, claims 15-61 are pending, and the remaining claims 1-14 have been cancelled. All pending claims stand rejected, leaving no claims allowed. The claims on appeal are claims 15-61.

IV. Status of Amendments

All amendments have been entered.

V. Summary of Invention

In its broadest sense, the invention, as defined in the claims on appeal, is directed to a catheter assembly that includes an elongate catheter and an expandable electrode body mounted to the catheter. The electrode body comprises an enlarged circumferential region or pronounced ring that defines a primarily distal facing surface (i.e., a surface that faces primarily in the distal direction). The distal facing surface includes an area configured to emit radio frequency (RF) energy. The invention lends itself well to the therapeutic ablation of tissue in and around the openings of blood vessels. In this case, the distal facing surface can be placed into firm contact

with the outside of the opening of a vessel to ensure that the entire opening of the vessel is ablated. Although it should not be limited to the preferred embodiments described in the specification, the invention will now be described in terms of the preferred embodiments in order to aid in further understanding the invention.

The specification at page 98, line 19 to page 103, line 24 describes the basic embodiment of the invention. As illustrated in Figs. 82 and 83, a tissue ablation catheter assembly 1500 comprises a catheter tube 1506 and a distally mounted expandable-collapsible body 1508, the center portion of which forms a pronounced ring 1514. The ring 1514 comprises a distally facing surface 1516 (i.e., a surface that faces in the distal direction) and a proximally facing surface 1518 (i.e., a surface that faces in the proximal direction), and divides the body 1508 into a distal region 1520 and a proximal region 1522. The circumference of the ring 1514 is greater than the circumference of the opening of the vessel in which the body 1508 is intended to ablate in and around, so that the distally facing surface 1516 of the ring 1514 rests against the tissue outside the opening of the vessel as the distal region 1520 of the body 1508 is inserted into the vessel, as illustrated in Fig. 94. The distally facing surface 1516 and distal region 1520 are configured to emit RF energy, whereas the proximally facing surface 1518 and proximal region 1522 are not configured to emit RF energy. This can be accomplished, e.g., by applying a conductive shell 1524 only to the distal facing surface 1516 and distal region 1520, or by forming the distal facing surface 1516 and distal region 1520 with a RF emitting microporous structure. In this manner, all of the RF energy will be focused at the distally facing surface 1516 and distal region 1520, which presumably will be in firm contact with the tissue to be ablated within and around the opening of the vessel.

VI. Issues

A. Whether claims 15-19, 21-25, 27-31, 33-37, 39-47, 49-53, and 55-61 are unpatentable under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 6,012,457 ("Lesh")?

B. Whether claims 20, 32, and 48 are unpatentable under 35 U.S.C. §103 as being obvious over Lesh in view of U.S. Patent No. 5,908,445 ("Whayne '445").

C. Whether claims 26, 38, and 54 are unpatentable under 35 U.S.C. §103 as being obvious over Lesh in view of U.S. Patent No. 5,853,411 ("Whayne '411").

VII. Grouping of Claims

Appellant believes that the following groups of claims are patentably distinct from each other:

A. Claims 15, 16, 19, 20, 22-28, 31, 32, 34-44, 47, 48, and 50-58

B. Claims 17, 18, 29, 30, 45, and 46

C. Claims 21, 33, and 49

D. Claims 59-61

VIII. Arguments

A. Claims 15-19, 21-25, 27-31, 33-37, 39-47, 49-53, and 55-61

Appellant respectfully submits that the Examiner erred in rejecting claims 15-19, 21-25, 27-31, 33-37, 39-47, 49-53, and 55-61 under 35 U.S.C. §102 as being anticipated by Lesh.

In concluding that Lesh anticipates the invention, the Examiner cites the embodiment illustrated in Figs. 8a-c of Lesh for disclosing an invasive catheter assembly that includes a catheter and an expandable electrode body having a pronounced ring with a distal facing surface

configured to emit RF energy. Appellant disagrees and contends that the Examiner has given the claim language "primarily distal facing surface" and unreasonable construction in concluding that the electrode body of Lesh includes such a feature. In particular, in response to Appellant's position that Lesh electrode body does not include a pronounced ring or enlarged circumferential region with a primarily distal facing surface, the Examiner indicated that the Fig. 8a embodiment of Lesh "clearly illustrates a circumferential region that occupies most of the distal surface of the device and therefore, has a primarily distal facing surface." (see Office Action, dated April 13, 2004, bottom of page 3). It appears from this statement that the Examiner has construed this limitation to require the pronounced ring or circumferential region to merely have a "primarily distal surface." In doing so, the Examiner has completely ignored the term "facing." When properly read with the term "facing," however, it is clear that this limitation requires the pronounced ring or circumferential region to have a surface that primarily faces in the distal direction."

A review of Fig. 8a of Lesh reveals that no portion of the circumferential ablation element 352 of the Lesh electrode body 350 faces primarily in the distal direction, and appears to actually face primarily in the radial direction. Given that Lesh does not disclose each and every element of the claimed invention, Appellant respectfully believes that independent claims 15, 27, and 43, as well as the claimed depending therefrom (claims 16-19, 21-25, 28-31, 33-37, 39-42, 44-47, 49-53, and 55-61), are patentable over Lesh.

Further, claims 17, 18, 29, 30, 45, and 46 additionally require the distal facing surface to comprise multiple RF energy emitting areas. In contrast, the surface of the circumferential

ablation element 352 of the Lesh electrode body 350 only comprises a single RF energy emitting area, and the Examiner has not stated otherwise.

Claims 21, 33, and 49 additionally require an interior support structure to be disposed within the interior region of the electrode body and configured to urge the electrode body into an expanded geometry to form the enlarged circumferential region or pronounced ring. In contrast, the Lesh electrode body 350 is not disclosed as having such interior support structure, and the Examiner has not stated otherwise.

Claims 59-61 additionally require the distal facing surface to extend along a plane perpendicular to the longitudinal axis of the elongate catheter. To the extent that any portion of the ablation element 352 of the Lesh electrode body 350 can be considered to extend along a plane, such plane is not perpendicular to the longitudinal axis of the catheter. In stark contrast, the distal facing surface 1516 of the pronounced ring 1514 in the preferred embodiment of the invention clearly extends along a plane that is perpendicular to the longitudinal axis of the catheter 1506.

Thus, the additional patentable features recited in claims 7, 18, 29, 30, 45, and 46, claims 21, 33, and 49, and claims 59-61, provide a further basis for the patentability of these claims over Lesh.

B. Claims 20, 32, and 48

Appellant respectfully submits that the Examiner erred in rejecting claims 20, 32, and 48 under 35 U.S.C. §103 as being obvious over Lesh in view of Whayne '445. As discussed above, Lesh does not disclose an electrode body that defines a pronounced ring or enlarged circumferential region with a primarily distal facing surface configured to emit RF energy, and

Whayne '445 does not supplement this lack of teaching. Thus, Appellant submits that claims 20, 32, and 48, which depend from respective independent claims 15, 27, and 43, are believed to be patentable over the combination of Lesh and Whayne '445.

C. Claims 26, 38, and 54

Appellant respectfully submits that the Examiner erred in rejecting claims 26, 38, and 54 under 35 U.S.C. §103 as being obvious over Lesh in view of Whayne '411. As discussed above, Lesh does not disclose an electrode body that defines a pronounced ring or enlarged circumferential region with a primarily distal facing surface configured to emit RF energy, and Whayne '411 does not supplement this lack of teaching. Thus, Appellant submits that claims 26, 38, and 54, which depend from respective independent claims 15, 27, and 43, are believed to be patentable over the combination of Lesh and Whayne '411.

Respectfully submitted,

Bingham McCutchen LLP

Dated: 8/18/04

By: _____
Michael J. Bolan
Reg. No. 42,339

Bingham McCutchen LLP
Three Embarcadero Center
San Francisco, California 94111

IX. Appendix of Claims Involved in the Appeal

1-14. (Cancelled)

15. A catheter assembly, comprising:

an elongate catheter; and

an expandable electrode body mounted proximate one end of the catheter, the electrode body configured to form a pronounced ring when expanded, the pronounced ring defining a primarily distal facing surface of the electrode body, wherein the distal facing surface includes an area configured to emit radio frequency (RF) energy.

16. The catheter assembly of claim 15, wherein the RF energy emitting area occupies substantially all of the distal facing surface.

17. The catheter assembly of claim 15, wherein the distal facing surface comprises multiple RF energy emitting areas.

18. The catheter assembly of claim 17, wherein each of the RF energy emitting areas composes a conductive substance disposed on the distal facing surface.

19. The catheter assembly of claim 15, wherein the RF energy emitting area comprises a conductive substance disposed on the distal facing surface.

20. The catheter assembly of claim 15, wherein the electrode body comprises a wall enclosing an interior region, the catheter comprises a lumen accessing the interior region, and the RF energy emitting area comprises a microporous section of the wall located in the distal facing surface.

21. The catheter assembly of claim 15, wherein the electrode body comprises a wall enclosing an interior region, the assembly further comprising an interior support structure disposed in the interior region of the electrode body and adapted to urge the electrode body into an expanded geometry to thereby form the enlarged circumferential region.

22. The catheter assembly of claim 15, wherein the pronounced ring further defines a primarily proximal facing surface, and wherein substantially all of the distal facing surface and the distal region is conductive, and wherein substantially all of the proximal facing surface is non-conductive.

23. The catheter assembly of claim 15, wherein the elongate catheter includes a guide wire lumen and a distal guide wire section, the guide wire lumen disposed in the distal guide wire section.

24. The catheter assembly of claim 15, wherein the expandable electrode body further comprises a wall and an interior region, and wherein the elongate catheter comprises an inflation lumen having a distal end and a proximal end, the distal end of the inflation lumen terminating in the interior region.

25. The catheter assembly of claim 24, further comprising:

a handle having an inflation port, a proximal end of the elongate catheter mounted to the handle, the proximal end of the inflation lumen terminating in said inflation port; and

RF generator electrically coupled to the RF energy emitting area of the electrode body.

26. The catheter assembly of claim 25, further comprising:

a temperature sensing element disposed on the expandable electrode body; and

a controller electrically coupled to the temperature sensing element.

27. A catheter assembly, comprising:

an elongate catheter; and

an expandable electrode body mounted proximate one end of the catheter, the electrode body configured to form an enlarged circumferential region and a region distal to the circumferential region when expanded, the circumferential region having a maximum circumference greater than a maximum circumference of the distal region, the circumferential region defining a primarily distal facing surface of the electrode body, wherein the distal facing surface includes an area configured to emit radio frequency (RF) energy.

28. The catheter assembly of claim 27, wherein the RF energy emitting area occupies substantially all of the distal facing surface.

29. The catheter assembly of claim 27, wherein the distal facing surface comprises multiple RF energy emitting areas.

30. The catheter assembly of claim 29, wherein each of the RF energy emitting areas comprises a conductive substance disposed on the distal facing surface.

31. The catheter assembly of claim 27, wherein the RF energy emitting area comprises a conductive substance disposed on the distal facing surface.

32. The catheter assembly of claim 27, wherein the electrode body comprises a wall enclosing an interior region, the catheter comprises a lumen accessing the interior region, and the RF energy emitting area comprises a microporous section of the wall located in the distal facing surface.

33. The catheter assembly of claim 27, wherein the electrode body comprises a wall enclosing an interior region, the assembly further comprising an interior support structure disposed in the interior region of the electrode body and adapted to urge the electrode body into an expanded geometry to thereby form the enlarged circumferential region.

34. The catheter assembly of claim 27, wherein the enlarged circumferential region further defines a primarily proximal facing surface, and wherein substantially all of the distal facing surface and the distal region is conductive, and wherein substantially all of the proximal facing surface is non-conductive.

35. The catheter assembly of claim 27, wherein the elongate catheter includes a guide wire lumen and a distal guide wire section, the guide wire lumen disposed in the distal guide wire section.

36. The catheter assembly of claim 27, wherein the expandable electrode body further comprises a wall and an interior region, and wherein the elongate catheter comprises an inflation lumen having a distal end and a proximal end, the distal end of the inflation lumen terminating in the interior region.

37. The catheter assembly of claim 36, further comprising:

a handle having an inflation port, a proximal end of the elongate catheter mounted to the handle, the proximal end of the inflation lumen terminating in said inflation port; and

an RF generator electrically coupled to the RF energy emitting area of the electrode body.

38. The catheter assembly of claim 27, further comprising:

a temperature sensing element disposed on the expandable electrode body; and

a controller electrically coupled to the temperature sensing element.

39. The catheter assembly of claim 27, wherein the expandable electrode body is configured for ablating tissue outside of a vessel opening, and wherein the distal region and distal facing surface of the enlarged circumferential region are respectively configured to simultaneously engage the tissue inside and the tissue outside of the vessel opening.

40. The catheter assembly of claim 39, wherein the vessel opening is a pulmonary vein opening.

41. The catheter assembly of claim 27, wherein the expandable electrode body is configured for ablating tissue inside and outside of a vessel opening, and wherein the distal region and distal facing surface of the enlarged circumferential region are respectively configured to simultaneously engage the tissue inside and the tissue outside of the vessel opening.

42. The catheter assembly of claim 41, wherein the vessel opening is a pulmonary vein opening.

43. A catheter assembly, comprising:

an elongate catheter; and

an expandable electrode body mounted proximate one end of the catheter, the electrode body configured to form a pronounced ring and a region distal to the pronounced ring when expanded, the pronounced ring defining a primarily distal facing surface of the electrode body, wherein the distal facing surface includes an area configured to emit radio frequency (RF) energy.

44. The catheter assembly of claim 43, wherein the RF energy emitting area occupies

substantially all of the distal facing surface.

45. The catheter assembly of claim 43, wherein the distal facing surface comprises multiple RF energy emitting areas.

46. The catheter assembly of claim 45, wherein each of the RF energy emitting areas comprises a conductive substance disposed on the distal facing surface.

47. The catheter assembly of claim 43, wherein the RF energy emitting area comprises a conductive substance disposed on the distal facing surface.

48. The catheter assembly of claim 43, wherein the electrode body comprises a wall enclosing an interior region, the catheter comprises a lumen accessing the interior region, and the RF energy emitting area comprises a microporous section of the wall located in the distal facing surface.

49. The catheter assembly of claim 43, wherein the electrode body comprises a wall enclosing an interior region, the assembly further comprising an interior support structure disposed in the interior region of the electrode body and adapted to urge the electrode body into an expanded geometry to thereby form the pronounced ring.

50. The catheter assembly of claim 43, wherein the pronounced ring further defines a primarily proximal facing surface, and wherein substantially all of the distal facing surface and the distal region is conductive, and wherein substantially all of the proximal facing surface is non-conductive.

51. The catheter assembly of claim 43, wherein the elongate catheter includes a guide wire lumen and a distal guide wire section, the guide wire lumen disposed in the distal guide wire

section.

52. The catheter assembly of claim 43, wherein the expandable electrode body further comprises a wall and an interior region, and wherein the elongate catheter comprises an inflation lumen having a distal end and a proximal end, the distal end of the inflation lumen terminating in the interior region.

53. The catheter assembly of claim 52, further comprising:

a handle having an inflation port, a proximal end of the elongate catheter mounted to the handle, the proximal end of the inflation lumen terminating in said inflation port; and

an RF generator electrically coupled to the RF energy emitting area of the electrode body

54. The catheter assembly of claim 43, further comprising:

a temperature sensing element disposed on the expandable electrode body; and

a controller electrically coupled to the temperature sensing element.

55. The catheter assembly of claim 43, wherein the expandable electrode body is configured for ablating tissue outside of a vessel opening, and wherein the distal region and distal facing surface of the pronounced ring are respectively configured to simultaneously engage the tissue inside and the tissue outside of the vessel opening.

56. The catheter assembly of claim 55, wherein the vessel opening is a pulmonary vein opening.

57. The catheter assembly of claim 43, wherein the expandable electrode body is configured for ablating tissue inside and outside of a vessel opening, and wherein the distal region and distal facing surface of the pronounced ring are respectively configured to

simultaneously engage the tissue inside and the tissue outside of the vessel opening.

58. The catheter assembly of claim 57, wherein the vessel opening is a pulmonary vein opening.

59. The catheter assembly of claim 15, wherein the distal facing surface extends along a plane perpendicular to a longitudinal axis of the elongate catheter.

60. The catheter assembly of claim 27, wherein the distal facing surface extends along a plane perpendicular to a longitudinal axis of the elongate catheter.

61. The catheter assembly of claim 43, wherein the distal facing surface extends along a plane perpendicular to a longitudinal axis of the elongate catheter.